K113253

510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	November 1, 2011	
Device:	Trade Name:	ACE Axcel Clinical Chemistry System
	Classification:	Class 1
	Common/Classification Name:	Analyzer, Chemistry (Photometric, Discrete), For Clinical Use (21 C.F.R. § 862.2610) Product Code JJE
	Trade Name:	ACE Glucose Reagent
	Classification:	Class 2
	Common/Classification Name:	Hexokinase, Glucose (21 C.F.R. § 862.1345) Product Code CFR
	Trade Name:	ACE Ion Selective Electrode (ISE) Module
	Classification:	Class 2
	Common/Classification Name:	Electrode, Ion Specific, Sodium, Potassium, Chloride (21 C.F.R. § 862.1665, 862.1600, 862.1170) Product Codes JGS, CEM, CGZ
Predicate Devices:	Manufacturer for analyzer/reagent system predicate: Alfa Wassermann ACE plus ISE/Clinical Chemistry System ACE Reagents (K931786)	

Device Descriptions:	The ACE Axcel Clinical Chemistry System consists of two major components, the chemistry instrument and an integrated Panel PC. The instrument accepts the physical patient samples, performs the appropriate optical or potentiometric measurements on those samples and communicates that data to an integral Panel PC. The Panel PC uses keyboard or touch screen input to manually enter a variety of data, control and accept data from the instrument, manage and maintain system information and generate reports relative to patient status and instrument performance. The Panel PC also allows remote download of patient requisitions and upload of patient results via a standard interface. In the ACE Glucose Reagent assay, glucose in serum reacts with adenosine triphosphate in the presence of hexokinase and magnesium with the formation of glucose-6-phosphate and adenosine diphosphate. Glucose-6-phosphate dehydrogenase catalyzes the oxidation of glucose-6-phosphate with NAD^+ to form 6-phosphogluconate and NADH. NADH absorbs strongly at 340 nm, whereas NAD^+ does not. The total amount of NADH formed is proportional to the concentration of glucose in the sample. The increase in absorbance is measured bichromatically at 340 nm/378 nm. The ACE Ion Selective Electrode (ISE) Module is used with ACE CAL A and CAL B Calibration Solutions in the performance of a two-point calibration in order to measure concentrations of sodium, potassium and chloride in undiluted serum. The ISE module uses a potentiometric method to simultaneously measure sodium, potassium and chloride in undiluted serum. Each electrode uses an ion-specific membrane to measure the difference in ionic concentration between an inner electrolyte solution and the sample. This difference causes an electro-chemical potential to form on the membrane of the active electrode. The connection of the amplifier and ground (reference electrode) to the ion selective electrode forms the measuring system. The two-point calibration with CAL A and CAL B with precisely known ion concentrations (two-point calibration) and the measured voltage difference of the sample and CAL A are used to determine the ion concentration in the sample.
Intended Use:	Indications for Use: The ACE Axcel Clinical Chemistry System is an automated, discrete, bench-top, random access analyzer that is intended for *in vitro* diagnostic use in the quantitative determination of constituents in blood and other fluids.

	The ACE Glucose Reagent is intended for the quantitative determination of glucose concentration in serum using the ACE Axcel Clinical Chemistry System. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE Axcel Clinical System includes an Ion Selective Electrode (ISE) module for the measurement of sodium, potassium and chloride in undiluted serum. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. • Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance • Potassium measurements are used to monitor electrolyte balance and in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. • Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
Technological Characteristics:	The following is a description of the major features of the ACE Axcel Clinical Chemistry System: • System throughput is approximately 160 test results per hour for routine, single reagent chemistries. System throughput will be higher when the test workload includes ISE's. • The instrument has a capacity of 40 reagent containers on board. A reagent cooling system maintains the reagents at 12°C during instrument operation. • Reagent containers are identified by computer coded labels to simplify system operation. All reagents in the system must include an identification label on the container. • Sample and reagent sensing notify the operator of a depleted condition during operation. • The system performs analysis at a reaction temperature of 37°C. • An electrolyte subsystem capable of measuring sodium, potassium and chloride concentrations is included. • Primary draw tubes may be introduced one at a time into the system for closed tube sampling. Positive tube identification can be achieved with an optional barcode scanner. An aliquot volume sufficient for all tests ordered is transferred and stored and the closed tube is returned to the user.

	• Sample cups are introduced to the system one at a time or by sample ring segment. • Disposable cuvettes are loaded in bulk and then automatically injected as needed by a cuvette hopper system. The ACE Axcel clinical chemistry optical system is capable of monitoring a maximum of 48 cuvettes at one time. • The absorbance optical system is capable of absorbance measurements in a linear range of 0.0 to 2.0 absorbance units (at 0.67 cm pathlength). Sixteen wavelengths are measured simultaneously using a photodiode array. The ACE Glucose Reagent consists of a single reagent bottle. The reagent contains nicotinamide adenine dinucleotide (NAD^+), adenosine 5'-triphosphate (ATP), magnesium, hexokinase and glucose-6-phosphate dehydrogenase. The ACE Ion Selective Electrode (ISE) Module uses a potentiometric method to simultaneously measure sodium, potassium and chloride in undiluted serum. Each electrode uses an ion-specific membrane to measure the difference in ionic concentration between an inner electrolyte solution and the sample.
Performance Data:	Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE Axcel Clinical Chemistry System included precision, accuracy, and detection limit data. <u>ACE Glucose Reagent</u> <u>Precision</u>: In testing conducted at four glucose levels for 22 days, the within-run CV ranged from 1.0 to 1.4%, and total CV ranged from 1.0 to 1.9%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.3 to 2.2% and total CV ranged from 0.5 to 2.2%. <u>Accuracy</u>: In the correlation study, 122 samples with glucose values ranging from 6 to 729 mg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9998, a standard error estimate of 3.1, a confidence interval slope of 1.001 to 1.009, and a confidence interval intercept of -1.5 to 0.1. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9992 to 0.9998, standard error estimates of 3.6 to 7.0, confidence interval slopes of 0.972 to 1.021, and a confidence interval intercepts of -3.0 to 4.1. <u>Detection limit</u>: The detection limit was 3.1 mg/dL.

	ACE Axcel Sodium ISE Precision: In testing conducted at four sodium levels for 21 days, the within-run CV ranged from 0.4 to 1.0%, and total CV ranged from 0.8 to 1.4%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.6 to 1.0% and total CV ranged from 0.8 to 1.4%. Accuracy: In the correlation study, 113 samples with sodium values ranging from 45.1 to194.0 mmol/L were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9963, a standard error estimate of 1.65, a confidence interval slope of 0.992 to 1.024, and a confidence interval intercept of -3.60 to 0.92. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9917 to 0.9995, standard error estimates of 0.74 to 3.07, confidence interval slopes of 0.989 to 1.067, and a confidence interval intercepts of -8.85 to 2.30. ACE Axcel Potassium ISE Precision: In testing conducted at four potassium levels for 21 days, the within-run CV ranged from 0.6 to 3.5%, and total CV ranged from 1.3 to 3.5%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 1.0 to 1.6% and total CV ranged from 1.1 to 1.6%. Accuracy: In the correlation study, 115 samples with potassium values ranging from 1.57 to 14.20 mmol/L were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9974, a standard error estimate of 0.146, a confidence interval slope of 0.989 to 1.015, and a confidence interval intercept of -0.050 to 0.095. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9973 to 0.9996, standard error estimates of 0.064 to 0.182, confidence interval slopes of 0.960 to 1.035, and a confidence interval intercepts of -0.194 to 0.216.

	ACE Axcel Chloride ISE Precision: In testing conducted at four chloride levels for 21 days, the within-run CV ranged from 0.5 to 1.0%, and total CV ranged from 1.1 to 1.5%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.9 to 1.5% and total CV ranged from 1.1 to 2.6%. Accuracy: In the correlation study, 111 samples with chloride values ranging from 63.4 to 176.0 mmol/L were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9855, a standard error estimate of 2.05, a confidence interval slope of 0.939 to 1.002, and a confidence interval intercept of -1.07 to 5.63. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9885 to 0.9996, standard error estimates of 0.55 to 3.05, confidence interval slopes of 0.976 to 1.088, and a confidence interval intercepts of -8.16 to 2.22.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

ALFA WASSERMANN Diagnostic Technologies, Inc
c/o Hyman Katz
4 Henderson Drive
West Caldwell, NJ 07006

MAY 17 2012

Re: k113253
Trade Name: ACE Axcel Clinical Chemistry System, ACE Ion Selective Electrode (ISE) Module, ACE Glucose Reagent
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: CFR, JGS, CEM, CGZ, JJE
Dated: April 12, 2012
Received: April 13, 2012

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K113253

Device Name: ACE Axcel Clinical Chemistry System, ACE Ion Selective Electrode (ISE) Module, ACE Glucose Reagent

Indications for Use:
The ACE Axcel Clinical Chemistry System is an automated, discrete, bench-top, random access analyzer that is intended for *in vitro* diagnostic use in the quantitative measurement of general chemistry assays for clinical use in physician office laboratories or clinical laboratories.
The ACE Axcel Clinical System includes an Ion Selective Electrode (ISE) module for the measurement of sodium, potassium and chloride in serum. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

- Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance
- Potassium measurements are used to monitor electrolyte balance and in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
- Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

The ACE Glucose Reagent is intended for the quantitative determination of glucose concentration in serum using the ACE Axcel Clinical Chemistry System. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D)	AND/OR	Over-The-Counter Use. (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of *In vitro* Diagnostic Devices (OIVD)

Division Sign-Off
Office of *In vitro* Diagnostic Device
Evaluation and Safety

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